REMARKS

By Final Office Action mailed April 11, 2007 and Advisory Action mailed August 15, 2007, all pending claims stand rejected. Pursuant to 37 C.F.R. §1.114, Applicants hereby submit a Request for Continued Examination (RCE), for which this response is to serve as the accompanying submission.

Claims 1-68 were pending. Claims 19-20, 23-24, 53-54 and 57-58 have been amended. More specifically, claims 19-20 and 53-54 have been amended to include succinimidyl carbonate as an electrophilic group. Support for the amendments can be found, for example, in paragraph [0098] of the published application. Claims 23-24 and 57-58 have been amended to indicate that m (or n) can be 2 or 4. Support for the amendments can be found in, for example, Example 1-3. New claims 69-81 have been added. Support for new claims 69 and 71 can be found, for example, in paragraph [018] of the published application. Support for new claims 70 and 72 can be found throughout the specification as filed, and in particular, in Examples 1-3 and Figures 4-18. Support for new claims 73-81 can be found, for example, in paragraphs [0017] and [0143] of the published application. Upon entry of the above amendments, claims 1-81 will be pending. No new matter is being introduced.

Claims 1-68 are rejected under 35 U.S.C. 112, first paragraph, as allegedly not enabled[1]. In particular, the Actions assert that the full scope of the claimed first and second crosslinkable components is not enabled. More specifically, the Examiner states that "the specification does not provide enablement for every cross-linkable component having m nucleophilic groups, with m≥2 and every cross-linkable components having n cross-linkable [sic] groups so that n≥2 and m+n≥5…"

Applicants respectfully submit that the disclosure of the instant application is commensurate with the scope of the claims, which are directed to methods of using Applicants' ***patented*** crosslinkable components. More specifically, claim 1 is directed to a method of augmenting soft and hard tissue comprising: providing a first crosslinkable component and a

[1] By final Office Action mailed April 11, 2007, claims 1-68 were rejected as allegedly failing to comply with the written description requirement under 35 U.S.C. 112, first paragraph. However, the Examiner's analysis in support of the rejection was clearly based on non-enablement. By Advisory Action mailed August 11, 2007, the Examiner confirmed that the rejection was "one of scope" and the "specification does not provide enablement..."

second crosslinkable component, applying the two crosslinkable components to the tissue site and allowing them to crosslink in *situ*. Applicants submit that the steps recited in claim 1 can be carried out by a skilled person in the art without undue experimentation based on the teaching described in the specification and the general knowledge of such a skilled person.

Regarding the steps of providing a first crosslinkable component and a second crosslinkable component, Applicants submit that they had been found fully enabled by the Office when it granted U.S. Patent No. 6,534,591 (the '591 patent). The'591 patent is a parent application of the instant application and contains identical specification. Issued claim 1 of the '591 patent is directed to a crosslinking composition and contains identical language with respect to the first and second crosslinkable components of claim 1 presently under examination. Under 35 U.S.C. 282, a patent shall be presumed valid. As such, claim 1 as granted in the '591 patent is presumed to be in compliance with, among others, the enablement requirement under 35 U.S.C. 112, first paragraph. In other words, the Office has already found that the specification of the '591 patent enables the making and using of the first and second crosslinkable components. Accordingly, the steps of providing first and second crosslinkable components, as recited in claim 1 of the instant application, are also enabled by the same specification.

Regarding the steps of applying the crosslinkable components to a tissue site and allowing them to crosslink *in situ*, Applicants submit that they are specifically taught in, *e.g.*, paragraphs [0164] – [0171], and are also within the knowledge of a skilled person in the art. The claimed method provides bulk to a tissue. All that a skilled person needs to do is to apply (*e.g.*, by injection) the crosslinkable components to any tissue in need of augmentation, whereby the crosslinkable components crosslink by forming covalent bonds between their nucleophilic groups and electrophilic groups. The resulting crosslinked composition adds bulk to the tissue. Accordingly, Applicants submit that the specification has provided ample teaching for the skilled person to carry out the steps recited in claim 1, which are applicable to any tissue that needs to be augmented.

Likewise, claim 35 and new claim 73 are also directed to methods of using applicants' ***patented*** crosslinkable components. More specifically, claim 35 recites a step of applying the patented crosslinkable components to the tissue at a wound site to prevent adhesion.

Claim 71 recites steps of forming a crosslinked composition from the patented crosslinkable components and delivering the crosslinked composition to a tissue in need of augmentation. All the steps recited therein are either adequately taught in the specification or within the general knowledge of a skilled person in the art.

In view of the above discussion, Applicants respectfully submit that claims 1-81 are fully enabled by the specification as filed.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

A good faith effort has been made to place this application in condition for allowance. However, should any further issue require attention prior to allowance, the Examiner is requested to contact the undersigned at (206) 622-4900 to resolve the same.

Respectfully submitted,

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